

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BAYER INTELLECTUAL PROPERTY  
GMBH, BAYER PHARMA AG, and  
JANSSEN PHARMACEUTICALS, INC.,

Plaintiffs,

v.

AUROBINDO PHARMA LIMITED,  
AUROBINDO PHARMA USA, INC.,  
BRECKENRIDGE PHARMACEUTICAL,  
INC., INVAGEN PHARMACEUTICALS,  
INC., MICRO LABS LTD., MICRO LABS  
USA INC., MYLAN PHARMACEUTICALS  
INC., PRINSTON PHARMACEUTICAL  
INC., SIGMAPHARM LABORATORIES,  
LLC, TORRENT PHARMACEUTICALS,  
LIMITED, and TORRENT PHARMA INC.

Defendants.

C.A. No. 15-902-RGA  
CONSOLIDATED

**STIPULATION AND ORDER REGARDING INFRINGEMENT**

Plaintiffs Bayer Intellectual Property GmbH, Bayer Pharma AG, and Janssen Pharmaceuticals, Inc., (collectively, “Plaintiffs”) and Defendant Breckenridge Pharmaceutical, Inc. (“Breckenridge”) hereby STIPULATE, and request that the Court ORDER, as follows:

1. The rivaroxaban products that are the subject of Breckenridge’s ANDA No. 208220 (including any amendments or supplements thereto) (“Breckenridge’s ANDA Products”), as well as the active ingredient contained therein, infringe each of claims 1-6, 10, 14, 16, and 27 of U.S. Patent No. 7,157,456 (“the ’456 patent”), provided that the claim at issue is not proven invalid or unenforceable;
2. Breckenridge’s ANDA Products infringe each of claims 8, 17, 18, 19, and 28 of the ’456 patent, provided that the claim at issue is not proven invalid or unenforceable;

3. The manufacture of the active ingredient contained in Breckenridge's ANDA Products infringes each of claims 7, 11, 20, and 21 of the '456 patent, provided that the claim at issue is not proven invalid or unenforceable;

4. Breckenridge's ANDA Products, as well as the active ingredient contained therein, infringe claim 1 of U.S. Patent No. 7,585,860, provided that the claim at issue is not proven invalid or unenforceable;

5. Neither Breckenridge, nor MSN Laboratories Private Limited ("MSN"), the supplier of the active ingredient contained in Breckenridge's ANDA Products, shall be required to produce documents in response to the subpoena served on MSN on or about December 7, 2016 in connection with this action;

6. Breckenridge need not produce, in response to Plaintiffs' First Set of Requests for Production to Breckenridge, dated August 5, 2016, or otherwise, material from DMF #027807 or materials obtained from MSN concerning DMF #027807; and

7. Breckenridge need not produce, in response to Plaintiffs' First Set of Requests for Production to Breckenridge, dated August 5, 2016 or otherwise any further documents responsive to any document request except (subject to its stated objections) Request Nos. 3, 34-36. For clarity, however, Breckenridge shall supplement its document production with respect to any further correspondence or filings with the FDA in relation to its ANDA No. 208220, including any supplements or amendments to ANDA No. 208220 and any materials relating to the proposed package insert/labeling for Breckenridge's ANDA Products. Breckenridge shall also produce any documents it intends to rely upon in this litigation.

The parties make this stipulation without prejudice to or waiver of their rights on any appeal of any judgment of this Court, except with respect to the matters of infringement as stipulated herein.

IT IS HEREBY STIPULATED:

Dated: February 3, 2017

Dated: February 3, 2017

/s/ Rodger D. Smith II

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IT IS SO ORDERED this \_\_\_\_\_ day of \_\_\_\_\_, 2017.

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The Honorable Richard G. Andrews  
United States District Judge